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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/493,480	CHEEVER ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *93,97-103 and 107-130* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *93, 97-103, 107-118, 121, 122, 124-130* is/are rejected.

7)☒ Claim(s) *119,120 and 123* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed June 17, 2005 is acknowledged.

2. Claims 93, 97-103, 107-130 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

4. The rejection of claims 93, 97-103, 107-130 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

5. The rejection of claims 93, 97-103, 107-118, 121, 122, 124-130 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment to the claims.

6. The rejection of claims 93 97, 102, 103, 107, 112, 113, 117, and 118 under 35 U.S.C. 102(e) as being anticipated by Hudziak (U.S. Patent 6,015,567; issued Jan. 18, 2000; effective filing date May 19, 1989; cited in the IDS) is withdrawn in view of the amendment to the claims.

New Grounds of Rejection:

7. Claims 93, 97-103, 107-118, 121, 122, and 124-130 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the amendments to claims 93 and 103 introduce new matter into the specification as originally filed.

Claims 93 and 103 have been amended so that the claims are drawn to nucleic acids encoding a polypeptides comprising a HER-2/Neu fusion proteins, the HER-2/Neu fusion proteins consisting of a HER-2/Neu extracellular domain linked to either a HER-2/neu phosphorylation domain or a fragment of a HER-2/neu phosphorylation domain, and not comprising a HER-2/Neu transmembrane domain or any portion of a HER-2/Neu intracellular domain other than the phosphorylation domain, wherein the HER-2/Neu fusion protein comprises at least 90% identity to SEQ ID NO: 6 and wherein the HER-2/Neu fusion protein is capable of producing an immune response against a HER-2/Neu protein in a warm-blooded animal.

Applicants argue that support is provided for the addition of the phrase "or any portion of a HER-2/Neu intracellular domain other than the phosphorylation domain". Applicants assert that lack of non phosphorylation domain sequences from the intracellular domain is an inherent feature of the exemplified fusion proteins, and concludes that therefore, the description of a number of fusion proteins provides implicit support for the amendment to claims 93 and 103. This argument is not found persuasive, because the cliam must be considered as a whole with

regard to whether the specification provides adequate support. Claims 93 and 103 are drawn to nucleic acids encoding fusion proteins and the structure of the fusion proteins are set forth in the claims as proteins comprising a fusion construct, where the fusion construct has two or three parts: an extracellular domain, possibly a linker (see claims 97 and 107) and a phosphorylation domain. As a whole, the fusion protein must have at least 90% identity to SEQ ID NO: 6 (in the case of claim 93) or SEQ ID NO: 7 (in the case of claim 103). SEQ ID NO: 6 and SEQ ID NO: 7 do not have linker sequences between the extracellular domain portion and the phosphorylation domain portion. The part of the fusion proteins encoded by the claimed nucleic acids that is not set forth in the claims structurally is the linker portion, except by the following phrase "and not comprising a HER-2/Neu transmembrane domain or any portion of a HER-2/Neu intracellular domain other than the phosphorylation domain". Support is not found for the concept of describing the linker as "not comprising a HER-2/Neu transmembrane domain or any portion of a HER-2/Neu intracellular domain other than the phosphorylation domain", because "any portion" may be equivalent to one amino acid or several amino acids that happen to be found within the intracellular domain and then linked together. Therefore, the examples of fusion proteins provided by the specification are not representative examples of the genus of proteins that are to be encoded by the claimed nucleic acids.

8. Claims 93, 97-103, 107-118, 121, 122, and 124-130 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. The basis for this rejection is that the specification fails to provide support for the claimed genus of nucleic acids encoding fusion proteins comprising at least 90% identity to SEQ ID NO: 6 or SEQ ID NO: 7.

This rejection is reinstated. Previously, applicants have argued that because of the addition of the limitation that the fusion protein is capable of producing an immune response against a HER-2/Neu protein in a warm-blooded animal that the genus of nucleic acids encoding polypeptides comprising fusion proteins having 90% identity to SEQ ID NO: 6 or SEQ ID NO: 7 is fully supported by the specification.

For a genus of products to be adequately described, the specification must provide at least the structural features common to the members of the genus. This may be done by describing a representative number of species of the genus, or by providing partial structures, physical or chemical characteristics, or functional characteristics coupled with a known or disclosed correlation between structure and function. The specification fails to teach the critical features of SEQ ID NO: 6 or SEQ ID NO: 7 that must be included to make a fusion protein that falls within the scope of the claims. As the claims currently read, the claimed fusion proteins encompass a structure that has high similarity to one domain of the fusion protein, fused to, perhaps, only one amino acid from the other domain. The specification lacks a definition of the scope of a Her-2 extracellular domain and also the scope of a Her-2 phosphorylation domain; specifically the specification fails to teach how much of the extracellular or phosphorylation domain may be missing and still be defined as such. Furthermore, the definition of the human and rat extracellular domains and phosphorylation domains is not a definition of all Her-2 extracellular domains or all Her-2 phosphorylation domains.

The addition of the limitation that the fusion protein be capable of producing an immune response against a HER-2/Neu protein in a warm-blooded animal does not add a limitation that adequately defines the genus. This is because the production of an immune response against a HER-2/Neu protein may only define a small region of the overall protein structure. There is no discussion in the specification pointing to a correlation between structure and function of a fusion protein consisting an extracellular domain and a phosphorylation domain (or a portion of a phosphorylation domain) having alterations in the amino acid sequence and fusion proteins capable of producing an immune response against a HER-2/Neu protein. Because of the 90% identity clause, the claims appear to contain a contradiction. On the one hand, the claims are drawn to nucleic acids encoding fusion proteins *consisting of* an extracellular domain and a phosphorylation domain, but on the other hand the claimed nucleic acid sequences encode fusion proteins that allow alterations. When is an extracellular domain or a phosphorylation domain an extracellular domain or a phosphorylation domain and when is it not? The addition of the limitation that the fusion protein be capable of producing an immune response against a HER-2/Neu protein fails to couple the structural characteristics with functional characteristics of the genus. Furthermore, the specification allows that percent identity to be measured over the regions of a protein sequence, and not necessarily over the entire length of the protein (page 9, lines 18-26). Therefore, one part of the fusion protein may produce an immune response against a HER-2/Neu protein, but the other part could have very little in common with SEQ ID NO: 6 or SEQ ID NO: 7.

Conclusion

No claim is allowed. Claims 119, 120 and 123 are objected to for depending on rejected claims.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
August 11, 2005

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER